AUG 1 8 2005

DIOMED

K051996

510(k) Summary of Safety and Effectiveness for the Diomed Delta 15 and Delta 30 Lasers

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:	Diomed, Ltd. Building 2000 Beach Drive Cambridge Research Park Waterbeach Cambridge CB5 9TE United Kingdom
Contact Person:	Timothy G Phipps Address as above Telephone: +44 1223 729314 Fax: +44 1223 729329
Summary Preparation Date:	July 15, 2005

2. Names

Device Name:	Diomed Delta 15 Laser and Diomed Delta 30 Laser
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. Predicate Devices

The Diomed Delta 15and Diomed Delta 30 Lasers are substantially equivalent to the Diomed D15Plus and D30Plus Diode Lasers (K013499, K012398, K023543, K041957).

4. Device Description

The purpose of this Special 510(k) is to notify FDA of the proposed new Diomed Delta 15 and Diomed Delta 30 Lasers, which are equivalent replacements for the Diomed 15plus and 30plus. Like their predecessors, the Diomed Delta 15 and Diomed Delta 30 Lasers consist of a Class IV GaAlAs (Gallium Aluminium Arsenide) diode laser with a wavelength of 810 ± 20 nm and a visible light

(aiming beam) 5 milliwatt Class IIIa diode laser with a wavelength of 635 – 655 nm.

The Diomed Delta 15 and Diomed Delta 30 Lasers are made up of a treatment laser and aiming beam. The Diomed Delta 15 is a diode laser capable of delivering up to 119 J/cm^2 of pulsed radiation via a fiber optic hand piece or 15 W of continuous wave radiation via an optical fiber coupled to the laser aperture. The Diomed Delta 30 is a diode laser capable of delivering up to 400 J/cm^2 of pulsed radiation via a fiber optic hand piece or 30 W of continuous wave radiation via an optical fiber coupled to the laser aperture. Drawings and photographs of the Diomed Delta 15 and Diomed Delta 30 Lasers are included in the operator manual found in Appendix K

5. **Indications for Use**
The Diomed Delta 15 and Diomed Delta 30 Lasers are intended for use in delivering up to 15 or up to 30 Watts, respectively, of continuous wave or pulsed radiation to a flexible optical fiber or spot handpiece for use in ablation, incision, excision, coagulation and vaporisation of soft tissues in open and endoscopic surgical procedures, including EndoVenous Laser Treatment (EVLT).

6. **Performance Data**
The Diomed Delta 15 and Diomed Delta 30 lasers have undergone a comprehensive series of test protocols in order to qualify and validate the performance of the devices. The results of the qualification/validation demonstrates equivalent performance to the predicate devices which themselves have substantial clinical and market evidence of acceptable performance. The Diomed Delta 15 and Diomed Delta 30 are therefore validated for use on this basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2005

Mr. Timothy G. Phipps
Quality Assurance & Regulatory Affairs Director
Diomed, Ltd.
Building 2000, Beach Drive
Cambridge Research Park, Waterbeach
Cambridge, United Kingdom CB5 9TE

Re: K051996
Trade/Device Name: Diomed Delta 15 and Diomed Delta 30 Laser
Regulation Number: 21 CFR 807.92
Regulation Name: Content and format of a 510(k) summary
Regulatory Class: II
Product Code: GEX
Dated: July 15, 2005
Received: July 25, 2005

Dear Mr. Phipps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bucholtz for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DIOMED

Indications for Use

510(k) Number (if known): K 051996

Device Name: Diomed Delta 15 and Diomed Delta 30 Laser

Indications For Use:

- General Surgery
- Ophthalmology/Oculoplastic
- Urology
- Gastroenterology
- Gynecology
- Otorhinolaryngology
- Pulmonary/Thoracic
- Dermatology/Plastic Surgery
- Neurosurgery (coagulation only)
- Orthopedic
- Treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein.
- Treatment of incompetent refluxing veins in the superficial venous system in the lower limb

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for Helpherson

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K051996